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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,254	02/12/2004	Michael R. S. Hill	P-9485.05	5396

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EXAMINER	
PATTON, AMANDA K	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
05/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,254	HILL ET AL.	
	Examiner	Art Unit	
	Amanda Patton	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 40-51* is/are pending in the application.

4a) Of the above claim(s) *12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 40-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment dated September 17, 2007 and subsequent submittal of replacement drawings on October 17, 2007 is acknowledged. In response to Applicant's submission of replacement drawings, the objection to the specification has been withdrawn. In response to the submission of the corrected Information Disclosure Statement dated September 17, 2007 the IDS has been considered. In response to the amendment to claims 1, the rejection of claims 1-19 under 35 U.S.C. 112, second paragraph has been withdrawn. Claims 1-19 and 40-51 are currently pending in this application, with claims 12-19 having been withdrawn from consideration.

Claim Objections

Claims 43(a) and 43(b) are objected to because of the following informalities: There are two claim 43s. For the purposes of examination, claim 43(a) has been renumbered claim 42. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 and 40-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (USPN 5,913,876) in view of Weirneke et al. (USPN 5,571,150, as previously cited).

NOTE: The instant application claims priority to prior-filed applications no. 08/640,013 and 09/070,506. However, neither of these applications provide adequate support for the method step of "providing esophageal stimulation of a vagal nerve" as required by independent claims 1, 40, 46, and all subsequent dependent claims. Accordingly, claims 1-11 and 40-51 have been given the priority dated of September 26, 2000 as a benefit of Application No. 09/433,323, now USPN 6,532,388.

Regarding **claims 1-6 and 11**, Taylor discloses the claimed invention including (e.g. Col. 4, line 35 - Col. 5, line 40):

- Providing stimulation of a vagal nerve to adjust the beating of a heart to a first condition (e.g. Col. 4, lines 40-45);
- Performing the medical procedure on the heart (e.g. performing the arteriotomy, which is a medical procedure on the heart);

- Reducing esophageal stimulation of the vagal nerve (e.g. vagal stimulation is performed while making the arteriotomy, and thus is not performed, which is a form of reduction, after the performance of the arteriotomy);
- Providing stimulation of the heart to adjust the beating of the heart to a second condition (e.g. employ a heart pacing device to provide cooperative means for restarting the heart in accordance with the invention in the event that the heart is slow to revive after stimulus is removed from the vagal nerve; Col. 12, lines 18-24); and
- Providing stimulation of the vagal nerve a subsequent time in order to re-adjust the beating of the heart to the first condition (e.g. Col. 4, lines 59-63, wherein more than one stitch is performed and thus more than one stimulation is necessary).

Taylor does not disclose esophageal stimulation of the vagal nerve. Weirneke teaches that it was known in the art at the time the invention was made to stimulate the vagal nerve using an esophageal electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the esophageal vagal nerve stimulator in the device of Taylor, since such a modification would provide the system with a non-invasive way to stimulate the vagus nerve for providing the predictable results of a less invasive medical procedure with less risk of infection.

Neither Taylor nor Wernicke discloses the use of epicardial stimulation of the heart, rather Taylor discloses the stimulation of the heart in a "conventional fashion" (Col.12, lines 21-22. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include epicardial stimulation of the heart in the method of Taylor or Wernicke, since it was well known in the art at the time the invention was made to epicardially stimulate the

heart in a "conventional fashion" and since such a modification would provide the system with heart stimulation without insertion of a lead into the heart for providing the predictable results of a reduced risk of thrombosis.

Regarding **claims 7**, Taylor additionally teaches the administration of heparin during the medical procedure (e.g. Col. 4, lines 32-35).

Regarding **claim 8**, Taylor and Wernicke disclose the claimed invention except the selection of a drug from the group listed in claim 8. It would have been obvious to one having ordinary skill in the art to administer a local anesthetic during an open heart surgery, since it is well known in the art to apply anesthetics during open heart surgery and since such a modification would provide the system with the predictable results of maximizing the patient's comfort.

Regarding **claims 9-10**, Taylor and Wernicke disclose the claimed invention except a drug is naturally occurring (claim 9) and chemically synthesized (claim 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a drug that is naturally occurring and chemically synthesized because it is well known in the art to use naturally occurring and chemically synthesized drugs during medical procedures, and since such a modification would provide the system with the predictable results of obtaining and ensuring maximum patient comfort and safety.

Regarding **claims 40-45**, Taylor additionally teaches an invasive medical procedure.

Regarding **claims 46-51**, Taylor and Wernicke disclose the claimed invention but does not disclose expressly a medical procedure comprising an MRI or a CAT scan of the heart. It would have been an obvious matter of design choice to a person of ordinary skill in the art to

modify the method as taught by Taylor and Wernicke with the performance of an MRI or CAT scan of the heart, because Applicant has not disclosed that the performance of the MRI or CAT scan of the heart is critically different than the performance of the open heart surgery, or that it provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well during the medical procedure as taught by Taylor and Wernicke, because it provides a medical procedure and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Taylor and Wernicke. Therefore, it would have been an obvious matter of design choice to modify the medical procedure to obtain the invention as specified in the claims.

Response to Arguments

Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762